



January 27, 2016

Norm Frederick
Pennsylvania Department of Environmental Protection
Bureau of Air Quality – Title V Section
Northeast Regional Office
2 Public Square
Wilkes-Barre, PA 18711-0790

RECEIVED

JAN 28 2016

Air Protection Division

RE: Annual Certification of Compliance – Calendar Year 2015
Semi-Annual Title V Deviation Report – July – December 2015
Quarterly Deviation Report – October – December 2015
B. Braun Medical Inc. (TVOP 39-00055)

Dear Mr. Frederick:

B. Braun Medical Inc. (B. Braun) operates a surgical and medical instrument apparatus manufacturing facility in Allentown, Pennsylvania. The B. Braun facility operates pursuant to the permit application shield provisions of Title V Operating Permit Number 39-00055, which was issued on January 13, 2010 and expired on January 13, 2015. A timely and complete Title V Renewal Application was submitted on July 9, 2014.

Please find enclosed for submittal to the Pennsylvania Department of Environmental Protection (PADEP) the Title V Compliance Certification for B. Braun's Allentown, PA facility covering the reporting period from January 1, 2015 through December 31, 2015. The purpose of this submittal is to jointly satisfy the requirements to submit an Annual Compliance Certification for the period of January 1, 2015 through December 31, 2015, a Semi-Annual Deviation report for the period of July 1, 2015 through December 31, 2015, and a Quarterly Deviation Report for the period of October 1, 2015 through December 31, 2015.

If you have any questions, please do not hesitate to call me at 610.596.2584.

Sincerely,

A handwritten signature in blue ink, appearing to read 'D. Lauer', written over a horizontal line.

B. Braun Medical, Inc.
David R. Lauer
Environmental Health and Safety Manager, PA Operations

Cc: Lindsey W. Kroos – All4 Inc.
Tara Quinlivan – PADEP
Enforcement Program Section – USEPA



PENNSYLVANIA DEPARTMENT OF ENVIRONMENTAL PROTECTION
BUREAU OF AIR QUALITY
COMPLIANCE CERTIFICATION FORM
 (25 Pa. Code § 127.513)

Plant Name:	B BRAUN MED INC/ALLENTOWN	Owner/Operator:	B BRAUN MED INC
Tax ID/Plant:	23-2116774-1	DEP Facility ID:	514477
Contact Person:	DAVID R LAUER	Title:	EH&S MANAGER
Operating Permit #:	39-00055	Phone Number:	(610) 596-2584

For the period *1/01/2015 – 12/31/2015*, **B BRAUN MED INC/ALLENTOWN** has been in continuous compliance with all applicable requirements of permit # **39-00055**, determined by the method(s) of compliance specified in said permit, except for the following deviations, exceedances and excursions:

Sect./Cond. #	Citation #	Source	Noncompliance	Monitoring Method(s)	Date	Duration	Corrective Action(s)

Certification of Truth, Accuracy and Completeness

Subject to the penalties of Title 18 Pa. C.S. Section 4904 and 35 P.S. Section 4009 (b) (2), I certify under penalty of law that, based on information and belief formed after reasonable inquiry, the statements and information contained in this form are true, accurate, and complete.

Name:	Rex Boland	Title:	Vice President/General Manager PA Operations
Signed:	<i>Rex A. Boland</i>	Date:	<i>1-27-16</i>

This certification must be signed by a responsible official. Any certification submitted without a valid signature will be returned.
The owner/operator shall identify any other material information needed in this certification to also comply with section 113(c)(2) of the Clean Air Act. If more spaces are needed, complete additional pages using the format shown in Addendum 1. This certification does not replace requirements pertaining to the submission of malfunction and CEM reports. DO NOT include that information on this form.

Citation	Permit Section	Terms & Conditions Contained in the Permit	Means of Determining Compliance Status	Compliance with Terms & Conditions was:
[25 Pa. Code §§ 127.412, 127.413, 127.414, 127.446(e) & 127.503] (Permit Renewal)	Section B (#004)	(a) An application for the renewal of the Title V permit shall be submitted to the Department at least six (6) months, and not more than 18 months, before the expiration date of this permit. The renewal application is timely if a complete application is submitted to the Department's Regional Air M...	<i>B. Braun submitted a renewal application at least six months, and not more than 18 months, before the expiration date of this permit (i.e., between July 13, 2013 and July 13, 2014). Additionally, an amended renewal application was submitted to the PADEP on December 11, 2014. Comments on the Draft Title V Operating Permit were submitted to PADEP on April 28, 2015.</i>	<input checked="" type="checkbox"/> Continuous <input type="checkbox"/> Intermittent
[25 Pa. Code § 127.513, 35 P.S. § 4008 and § 114 of the CAA] (Inspection and Entry)	Section B (#006)	(a) Upon presentation of credentials and other documents as may be required by law for inspection and entry purposes, the permittee shall allow the Department of Environmental Protection or authorized representatives of the Department to perform the following: (1) Enter at reasonable times upo...	<i>B. Braun allows department representatives onsite during reasonable times as requested.</i>	<input checked="" type="checkbox"/> Continuous <input type="checkbox"/> Intermittent
[25 Pa. Code §§ 127.25, 127.444, & 127.512(c)(1)] (Compliance Requirements)	Section B (#007)	(a) The permittee shall comply with the conditions of this permit. Noncompliance with this permit constitutes a violation of the Clean Air Act and the Air Pollution Control Act and is grounds for one (1) or more of the following: (1) Enforcement action (2) Permit termination, revocation...	<i>This report serves as the means to determine compliance with this requirement.</i>	<input checked="" type="checkbox"/> Continuous <input type="checkbox"/> Intermittent
[25 Pa. Code §§ 127.411(d) & 127.512(c)(5)] (Duty to Provide Information)	Section B (#009)	(a) The permittee shall furnish to the Department, within a reasonable time, information that the Department may request in writing to determine whether cause exists for modifying, revoking and reissuing, or terminating the permit, or to determine compliance with the permit. (b) Upon request, the ...	<i>B. Braun maintains and can make available upon request required records and other information.</i>	<input checked="" type="checkbox"/> Continuous <input type="checkbox"/> Intermittent

Citation	Permit Section	Terms & Conditions Contained in the Permit	Means of Determining Compliance Status	Compliance with Terms & Conditions was:
[25 Pa. Code § 127.541] (Significant Operating Permit Modifications)	Section B (#012)	When permit modifications during the term of this permit do not qualify as minor permit modifications or administrative amendments, the permittee shall submit an application for significant Title V permit modifications in accordance with 25 Pa. Code § 127.541.	N/A – this condition is explanatory and does not provide any means by which B. Braun can certify continuous or intermittent compliance. No significant Title V permit modification applications were required to be submitted during the reporting period.	<input type="checkbox"/> Continuous <input type="checkbox"/> Intermittent
[25 Pa. Code §§ 127.704, 127.705 & 127.707] (Fee Payment)	Section B (#016)	(a) The permittee shall pay fees to the Department in accordance with the applicable fee schedules in 25 Pa. Code Chapter 127, Subchapter I (relating to plan approval and operating permit fees). (b) Emission Fees. The permittee shall, on or before September 1st of each year, pay applicable annual....	B. Braun demonstrates compliance by maintaining accounting records.	<input checked="" type="checkbox"/> Continuous <input type="checkbox"/> Intermittent
[25 Pa. Code §§ 127.14(b) & 127.449] (Authorization for De Minimis Emission Increases)	Section B (#017)	(a) This permit authorizes de minimis emission increases from a new or existing source in accordance with 25 Pa. Code §§ 127.14 and 127.449 without the need for a plan approval or prior issuance of a permit modification. The permittee shall provide the Department with seven (7) days prior written ...	B. Braun continues to maintain records to demonstrate that VOC emissions do not exceed the de minimis threshold from May 2011 & August 2013 RFD approvals.	<input checked="" type="checkbox"/> Continuous <input type="checkbox"/> Intermittent
[25 Pa. Code §§ 127.11a & 127.215] (Reactivation of Sources)	Section B (#018)	(a) The permittee may reactivate a source at the facility that has been out of operation or production for at least one year, but less than or equal to five (5) years, if the source is reactivated in accordance with the requirements of 25 Pa. Code §§ 127.11a and 127.215. The reactivated source will....	B. Braun submitted a Maintenance and Reactivation Plan to PADEP July 10, 2015 for Source ID 114 (Emergency Generator)	<input checked="" type="checkbox"/> Continuous <input type="checkbox"/> Intermittent
[25 Pa. Code §§ 121.9 & 127.216] (Circumvention)	Section B (#019)	(a) The owner of this Title V facility, or any other person, may not circumvent the new source review requirements of 25 Pa. Code Chapter 127, Subchapter E by causing or allowing a pattern of ownership or development, including the phasing, staging, delaying or engaging in incremental construction,....	N/A – this condition is explanatory and does not provide any means by which B. Braun can certify continuous or intermittent compliance.	<input type="checkbox"/> Continuous <input type="checkbox"/> Intermittent

Citation	Permit Section	Terms & Conditions Contained in the Permit	Means of Determining Compliance Status	Compliance with Terms & Conditions was:
[25 Pa. Code §§ 127.402(d) & 127.513(1)] (Submissions)	Section B (#020)	(a) Reports, test data, monitoring data, notifications and requests for renewal of the permit shall be submitted to the: Regional Air Program Manager PA Department of Environmental Protection (At the address given on the permit transmittal letter, or otherwise notified) (b) Any report...	<i>B. Braun certifies and submits reports to applicable locations identified in this condition.</i>	<input checked="" type="checkbox"/> Continuous <input type="checkbox"/> Intermittent
[25 Pa. Code §§ 127.441(c) & 127.463(e); Chapter 139; & 114(a)(3), 504(b) of the CAA] (Sampling, Testing and Monitoring Procedures)	Section B (#021)	(a) The permittee shall perform the emissions monitoring and analysis procedures or test methods for applicable requirements of this Title V permit. In addition to the sampling, testing and monitoring procedures specified in this permit, the Permittee shall comply with any additional applicable re...	<i>B. Braun demonstrates compliance by maintaining records of sampling, testing, and monitoring performed at the facility.</i>	<input checked="" type="checkbox"/> Continuous <input type="checkbox"/> Intermittent
[25 Pa. Code §§ 127.511 & Chapter 135] (Recordkeeping Requirements)	Section B (#022)	(a) The permittee shall maintain and make available, upon request by the Department, records of required monitoring information that include the following: (1) The date, place (as defined in the permit) and time of sampling or measurements. (2) The dates the analyses were performed. ...	<i>B. Braun maintains and can make available upon request all required records.</i>	<input checked="" type="checkbox"/> Continuous <input type="checkbox"/> Intermittent
[25 Pa. Code §§ 127.411(d), 127.442, 127.463(e) & 127.511(c)] (Reporting Requirements)	Section B (#023)	(a) The permittee shall comply with the reporting requirements for the applicable requirements specified in this Title V permit. In addition to the reporting requirements specified herein, the permittee shall comply with any additional applicable reporting requirements promulgated under the Clean ...	<i>B. Braun demonstrates compliance by maintaining records of all required reporting.</i>	<input checked="" type="checkbox"/> Continuous <input type="checkbox"/> Intermittent
[25 Pa. Code § 127.513] (Compliance Certification)	Section B (#024)	(a) One year after the date of issuance of the Title V permit, and each year thereafter, unless specified elsewhere in the permit, the permittee shall submit to the Department and EPA Region III a certificate of compliance with the terms and conditions in this permit, for the previous year, includi...	<i>This report serves as the certification of compliance required by this condition. Consistent with Permit Condition #015 of Section C, B. Braun submits this report by January 30 of each year.</i>	<input checked="" type="checkbox"/> Continuous <input type="checkbox"/> Intermittent

Citation	Permit Section	Terms & Conditions Contained in the Permit	Means of Determining Compliance Status	Compliance with Terms & Conditions was:
[25 Pa. Code §§ 127.441(d), 127.512(i) and 40 CFR Part 68] (Risk Management)	Section B (#026)	(a) If required by Section 112(r) of the Clean Air Act, the permittee shall develop and implement an accidental release program consistent with requirements of the Clean Air Act, 40 CFR Part 68 (relating to chemical accident prevention provisions) and the Federal Chemical Safety Information, Site S...	N/A – B. Braun is not subject to the Risk Management requirements.	<input type="checkbox"/> Continuous <input type="checkbox"/> Intermittent
[25 Pa. Code §123.1] (Prohibition of certain fugitive emissions)	Section C - I. Restrictions - Emission Restriction(s) (#001)	<p>The permittee may not permit the emission into the outdoor atmosphere of a fugitive air contaminant from a source other than the following:</p> <p>(1) Construction or demolition of buildings or structures.</p> <p>(2) Grading, paving and maintenance of roads and streets.</p> <p>(3) Use of roads and streets. Emissions f...</p>	B. Braun demonstrates compliance by recording results of weekly visual observations in a weekly inspection log.	<input checked="" type="checkbox"/> Continuous <input type="checkbox"/> Intermittent
[25 Pa. Code §123.2] (Fugitive particulate matter)	Section C - I. Restrictions - Emission Restriction(s) (#002)	The permittee may not permit fugitive particulate matter to be emitted into the outdoor atmosphere from a source specified in Site Level Condition #001, if such emissions are visible at the point the emissions pass outside the person's property.	B. Braun demonstrates compliance by recording results of weekly visual observations in a weekly inspection log.	<input checked="" type="checkbox"/> Continuous <input type="checkbox"/> Intermittent
[25 Pa. Code §123.31] (Limitations)	Section C - I. Restrictions - Emission Restriction(s) (#003)	The permittee may not permit the emission into the outdoor atmosphere of any malodorous air contaminants from any source in such a manner that the malodors are detectable outside the property of the person on whose land the source is being operated.	B. Braun demonstrates compliance by recording results of observations in a weekly inspection log and by having no documented complaints of malodors outside the property line.	<input checked="" type="checkbox"/> Continuous <input type="checkbox"/> Intermittent
[25 Pa. Code §123.41] (Limitations)	Section C - I. Restrictions - Emission Restriction(s) (#004)	<p>The permittee may not permit the emission into the outdoor atmosphere of visible air contaminants in such a manner that the opacity of the emission is either of the following:</p> <p>(1) Equal to or greater than 20% for a period or periods aggregating more than three minutes in any 1 hour.</p> <p>(2) Equal ...</p>	B. Braun demonstrates compliance by recording results of weekly visual observations in a weekly inspection log.	<input checked="" type="checkbox"/> Continuous <input type="checkbox"/> Intermittent

Citation	Permit Section	Terms & Conditions Contained in the Permit	Means of Determining Compliance Status	Compliance with Terms & Conditions was:
[25 Pa. Code §123.42] (Exceptions)	Section C - I. Restrictions - Emission Restriction(s) (#005)	The limitations of Site Level Condition #004 shall not apply to a visible emission in any of the following instances: (1) when the presence of uncombined water is the only reason for failure of the emission to meet the limitations. (2) When the emission results from the operation of equipment ...	N/A – this condition is explanatory and does not provide any means by which B. Braun can certify continuous or intermittent compliance.	<input type="checkbox"/> Continuous <input type="checkbox"/> Intermittent
[25 Pa. Code §127.511] (Monitoring and related recordkeeping and reporting requirements.)	Section C - II. Testing Requirements (#006)	All sampling, testing and analysis performed in compliance with the requirements of any section of this permit shall be done in accordance with General Title V Requirements #021.	B. Braun performs all sampling, testing, and analysis in compliance with the requirements of the facility's permit.	<input checked="" type="checkbox"/> Continuous <input type="checkbox"/> Intermittent
[25 Pa. Code §139.1] (Sampling facilities.)	Section C - II. Testing Requirements (#007)	Upon the request of the Department, the person responsible for a source shall provide adequate sampling ports, safe sampling platforms and adequate utilities for the performance by the Department of tests on such source. The Department will set forth, in the request, the time period in which the fac...	B. Braun can provide sampling facilities upon request. No tests were requested by the department during the reporting period.	<input checked="" type="checkbox"/> Continuous <input type="checkbox"/> Intermittent
[25 Pa. Code §139.2] (Sampling by others.)	Section C - II. Testing Requirements (#008)	Sampling and testing done by persons other than the Department may be accepted by the Department provided that: (1) The Department has been given reasonable notice of the sampling and testing and has been given reasonable opportunity to observe and participate in the sampling and testing.	N/A – this condition is explanatory and does not provide any means by which B. Braun can certify continuous or intermittent compliance. B. Braun notifies PADEP prior to sampling or testing.	<input type="checkbox"/> Continuous <input type="checkbox"/> Intermittent
[25 Pa. Code §123.43] (Measuring techniques)	Section C - III. Monitoring Requirements (#009)	Visible emissions may be measured using either of the following: (1) A device approved by the Department and maintained to provide accurate opacity measurements. (2) Observers, trained and qualified to measure plume opacity with the naked eye or with the aid of any devices approved by the ...	B. Braun measures visible emissions with the naked eye.	<input checked="" type="checkbox"/> Continuous <input type="checkbox"/> Intermittent

Citation	Permit Section	Terms & Conditions Contained in the Permit	Means of Determining Compliance Status	Compliance with Terms & Conditions was:
[25 Pa. Code §127.511] (Monitoring and related recordkeeping and reporting requirements.)	Section C - III. Monitoring Requirements (#010)	The permittee shall conduct a weekly inspection during daylight hours when the plant is in production to inspect for visible, fugitive, and malodor emissions. If visible, fugitive or malodor emissions are detected, corrective actions shall be taken immediately to abate the emission.	<i>B. Braun demonstrates compliance by recording results of weekly visual observations in a weekly inspection log.</i>	<input checked="" type="checkbox"/> Continuous <input type="checkbox"/> Intermittent
[25 Pa. Code §127.511] (Monitoring and related recordkeeping and reporting requirements.)	Section C - IV. Recordkeeping Requirements (#011)	All records, reports, and analysis results generated in compliance with the requirements of any section of this permit shall be maintained in accordance with General Title V Requirement #022, Section B, and shall be made available to the Department upon written or verbal request at a reasonable time...	<i>B. Braun maintains and can make available upon request required records of results of weekly visual observations.</i>	<input checked="" type="checkbox"/> Continuous <input type="checkbox"/> Intermittent
[25 Pa. Code §127.511] (Monitoring and related recordkeeping and reporting requirements.)	Section C - IV. Recordkeeping Requirements (#012)	All weekly inspection results for visible, fugitive, or malodor emissions, shall be recorded in a logbook. The logbook shall be maintained on-site and be made available to the Department upon request. At a minimum, the permittee shall record the date, time, results of the inspection, and individual ...	<i>B. Braun maintains and can make available upon request required records of results of weekly visual observations.</i>	<input checked="" type="checkbox"/> Continuous <input type="checkbox"/> Intermittent
[25 Pa. Code §127.511] (Monitoring and related recordkeeping and reporting requirements.)	Section C - V. Reporting Requirements (#013)	On a quarterly basis, the permittee shall compile a report of all logged instances of exceedance of the fugitive, visible and malodor emission limitations, as required by Site Level Conditions #001, #003 and #004, that occurred during the previous three (3) months. These reports shall be submitted t...	<i>B. Braun demonstrates compliance by maintaining records of all required reporting.</i>	<input checked="" type="checkbox"/> Continuous <input type="checkbox"/> Intermittent
[25 Pa. Code §127.511] (Monitoring and related recordkeeping and reporting requirements.)	Section C - V. Reporting Requirements (#014)	1) The company, within one hour of occurrence, shall notify the Department, at 610-861-2070, of any malfunction of the source(s) or associated air cleaning device(s) which results in, or may possibly be resulting in, the emission of air contaminants in excess of the limitations specified in, or esta...	<i>B. Braun demonstrates compliance by maintaining records of all required notifications.</i>	<input checked="" type="checkbox"/> Continuous <input type="checkbox"/> Intermittent
[25 Pa. Code §127.513] (Compliance certification.)	Section C - V. Reporting Requirements (#015)	Compliance certification The reporting period for the certificate of compliance required by condition #024 of Section B, shall be for the previous calendar year, and it shall be submitted within 60 days after the specified period but no later than March 1st.	<i>B. Braun demonstrates compliance by maintaining records of all required reporting.</i>	<input checked="" type="checkbox"/> Continuous <input type="checkbox"/> Intermittent

Citation	Permit Section	Terms & Conditions Contained in the Permit	Means of Determining Compliance Status	Compliance with Terms & Conditions was:
[25 Pa. Code §123.11] (Prohibition of certain fugitive emissions)	Section C - VI. Work Practice Standards (#016)	The permittee shall take all reasonable actions to prevent particulate matter from becoming airborne. These actions shall include, but not be limited to, the following: (1) Use, where possible, of water or chemicals for control of dust in the demolition of buildings or structures, construction ...	<i>B. Braun takes action to prevent particulate matter from becoming airborne if necessary. B. Braun demonstrates compliance by maintaining records of all required reporting.</i>	<input checked="" type="checkbox"/> Continuous <input type="checkbox"/> Intermittent
[25 Pa. Code §129.14] (Open burning operations)	Section C - VI. Work Practice Standards (#017)	(a) Air basins. No person may permit the open burning of material in an air basin. (b) Exceptions: The requirements of subsections (a) do not apply where the open burning operations result from: (1) A fire set to prevent or abate a fire hazard, when approved by the Department a...	<i>B. Braun does not conduct any open burning as it is not permitted by local authorities.</i>	<input checked="" type="checkbox"/> Continuous <input type="checkbox"/> Intermittent
[25 Pa. Code §127.512] (Operating permit terms and conditions.)	Section C - VII. Additional Requirements (#018)	Internal combustion engines regardless of size, with combined NOx emissions less than 100 lbs/hr, 1000 lbs/day, 2.75 tons per ozone season and 6.6 tons per year on a 12-month rolling basis for all exempt engines at the site.	<i>B. Braun demonstrates compliance by maintaining records of the hours of operation for each internal combustion engine to ensure they do not exceed the hourly limitations contained in Section E, GRP2 Condition #003, which prevents emissions from exceeding the thresholds in the condition.</i>	<input checked="" type="checkbox"/> Continuous <input type="checkbox"/> Intermittent
<p><i>The following conditions apply to GRP1, which includes the following emission units:</i></p> <ul style="list-style-type: none"> ▪ 101 - STERILIZER - 1000 CU FT ▪ 102 - STERILIZER - 1000 CU FT ▪ 103 - STERILIZER - 1000 CU FT ▪ 104 - STERILIZER - 1000 CU FT ▪ 105 - STERILIZER - 1200 CU FT ▪ 106 - STERILIZER - 1250 CU FT ▪ 107 - STERILIZER - 3700 CU FT ▪ 108 - STERILIZER - 130 CU FT ▪ 110 - AERATION ROOM 				

Citation	Permit Section	Terms & Conditions Contained in the Permit	Means of Determining Compliance Status	Compliance with Terms & Conditions was:
GRP1 [40 CFR Part 63 NESHAPS for Source Categories \$40 CFR 63.362] (Standards.)	Section D - I. Restrictions - Emission Restriction(s) (#001)	(a) Each owner or operator of a source subject to the provisions of this subpart shall comply with these requirements on and after the compliance date specified in Sec. 63.360(g). The standards of this section are summarized in Table 1 of this section. Table 1 of Section 63.362.-- Standards for...	<i>B. Braun demonstrates compliance maintaining the Deoxx Wet Scrubber according to manufacturer recommendations and replacing the catalyst of the Catalytic Oxidizer controlling the aeration room vent every five (5) years. The catalyst was replaced in March 2009 and 2014. The next replacement is required March 2019.</i>	<input checked="" type="checkbox"/> Continuous <input type="checkbox"/> Intermittent
GRP1 [40 CFR Part 63 NESHAPS for Source Categories \$40 CFR 63.365] (Test methods and procedures.)	Section D - II. Testing Requirements (#002)	(a) Performance testing. The owner or operator of a source subject to the emissions standards in Sec. 63.362 shall comply with the performance testing requirements in Sec. 63.7 of subpart A of this part, according to the applicability in Table 1 of Sec. 63.360, and in this section. (b) Effi...	<i>B. Braun demonstrates compliance by maintaining records of all testing performed according to General Title V Condition #022.</i>	<input checked="" type="checkbox"/> Continuous <input type="checkbox"/> Intermittent
GRP1 [40 CFR Part 63 NESHAPS for Source Categories \$40 CFR 63.363] (Compliance and performance provisions.)	Section D - III. Monitoring Requirements (#003)	(a) (1) The owner or operator of a source subject to emissions standards in Sec. 63.362 shall conduct an initial performance test using the procedures listed in Sec. 63.7 according to the applicability in Table 1 of Sec. 63.360, the procedures listed in this section, and the test methods listed ...	<i>B. Braun demonstrates compliance by maintaining records of the initial performance tests and of all testing performed according to General Title V Condition #022, as well as by recording the Deoxx Wet Scrubber liquid level once per week and monitoring and recording temperature data for the Catalytic Oxidizer.</i>	<input checked="" type="checkbox"/> Continuous <input type="checkbox"/> Intermittent
GRP1 [40 CFR Part 63 NESHAPS for Source Categories \$40 CFR 63.364] (Monitoring requirements.)	Section D - III. Monitoring Requirements (#004)	(a)(1) The owner or operator of a source subject to emissions standards in Sec. 63.362 shall comply with the monitoring requirements in Sec. 63.8 of subpart A of this part, according to the applicability in Table 1 of Sec. 63.360, and in this section. (2) Each owner or operator of an ethy...	<i>B. Braun demonstrates compliance by monitoring and recording the Deoxx Wet Scrubber liquid level once per week and monitoring and recording temperature data for the Catalytic Oxidizer.</i>	<input checked="" type="checkbox"/> Continuous <input type="checkbox"/> Intermittent

Citation	Permit Section	Terms & Conditions Contained in the Permit	Means of Determining Compliance Status	Compliance with Terms & Conditions was:
GRP1 [40 CFR Part 63 NESHAPS for Source Categories \$40 CFR 63.367] (Recordkeeping requirements.)	Section D - IV. Recordkeeping Requirements (#005)	(a) The owner or operator of a source subject to Sec. 63.362 shall comply with the recordkeeping requirements in Sec. 63.10(b) and (c), according to the applicability in Table 1 of Sec. 63.360, and in this section. All records required to be maintained by this subpart or a subpart referenced by ...	<i>B. Braun maintains and can make available upon request all required records.</i>	<input checked="" type="checkbox"/> Continuous <input type="checkbox"/> Intermittent
GRP1 [40 CFR Part 63 NESHAPS for Source Categories \$40 CFR 63.366] (Reporting requirements.)	Section D - V. Reporting Requirements (#006)	(a) The owner or operator of a source subject to the emissions standards in Sec. 63.362 shall fulfill all reporting requirements in Secs. 63.10(a), (d), (e), and (f) of subpart A, according to the applicability in Table 1 of Sec. 63.360. These reports will be made to the Administrator at the app...	<i>B. Braun demonstrates compliance by maintaining records of all required reporting.</i>	<input checked="" type="checkbox"/> Continuous <input type="checkbox"/> Intermittent
GRP1 [25 Pa. Code \$127.441] (Operating permit terms and conditions.)	Section D - VII. Additional Requirements (#007)	1. Minimum oxidation temperature for the Donaldson catalytic oxidizer shall be 253 deg F (low level EtO concentration) and 258 deg F (high level EtO concentration). 2. Chemrox Deoxx scrubber liquid level maximum shall be 126 inches.	<i>B. Braun demonstrates compliance by monitoring and recording the Deoxx Wet Scrubber liquid level once per week and monitoring and recording temperature data for the Catalytic Oxidizer.</i>	<input checked="" type="checkbox"/> Continuous <input type="checkbox"/> Intermittent
<i>The following conditions apply to GRP2, which includes the following emission units:</i>				
<ul style="list-style-type: none"> ▪ 003 – EMERGENCY GENERATOR – 605HP DIESEL ▪ 004 – FIRE PUMP – 100HP DIESEL ▪ 111 – EMERGENCY GENERATOR 2 ▪ 112 – EMERGENCY GENERATOR 1 ▪ 113 – FIRE PUMP ▪ 114 – EMERGENCY GENERATOR – KOHLER 30 KW; NATURAL GAS – B. Braun submitted a Maintenance and Reactivation Plan to the PADEP July 10, 2015 for Source ID 114 (Emergency Generator). Source ID 114 is no longer in use, but remains within the TVOP and is inspected every six months per the Maintenance and Reactivation Plan submitted to PADEP on July 10, 2015. 				
GRP2 [25 Pa. Code \$123.13] (Processes)	Section D - I. Restrictions - Emission Restriction(s) (#001)	The permittee may not permit the emission into the outdoor atmosphere of particulate matter, expressed as PM, from each source of this group in excess of the following rate: (i) .04 grain per dry standard cubic foot, when the effluent gas volume is less t...	<i>B. Braun demonstrates compliance by continued good operation and maintenance practices.</i>	<input checked="" type="checkbox"/> Continuous <input type="checkbox"/> Intermittent

Citation	Permit Section	Terms & Conditions Contained in the Permit	Means of Determining Compliance Status	Compliance with Terms & Conditions was:
GRP2 [25 Pa. Code §123.21] (General)	Section D - I. Restrictions - Emission Restriction(s) (#002)	The permittee may not permit the emission into the outdoor atmosphere of sulfur oxides from a source in a manner that the concentration of the sulfur oxides, expressed as SO ₂ , from each source of this group in excess of the following rate: ...	<i>B. Braun demonstrates compliance by verifying the type of fuel burned and its sulfur content.</i>	<input checked="" type="checkbox"/> Continuous <input type="checkbox"/> Intermittent
GRP2 [25 Pa. Code §127.441] (Operating permit terms and conditions.)	Section D - I. Restrictions - Operating Hours Restriction(s) (#003)	Each source in this group shall operate no more than 242 hours during the May 1 through September 30 ozone season of each year, and no more than 500 hours during any consecutive 12-month period.	<i>B. Braun demonstrates compliance by recording the total hours of operation for each source on a monthly basis pursuant to Condition #004.</i>	<input checked="" type="checkbox"/> Continuous <input type="checkbox"/> Intermittent
GRP2 [25 Pa. Code §127.441] (Operating permit terms and conditions.)	Section D - IV. Recordkeeping Requirements (#004)	The permittee shall record the total hours of operation for each source on a monthly basis. The data recorded shall include, but not be limited to: (1) The name of the source which was operated. (2) The hours of operation of each source.	<i>B. Braun maintains and can make available upon request all required records.</i>	<input checked="" type="checkbox"/> Continuous <input type="checkbox"/> Intermittent
GRP2 [25 Pa. Code §127.441] (Operating permit terms and conditions.)	Section D - VI. Work Practice Standards (#005)	The sources shall be operated in accordance with the manufacturers specification and the source shall also be operated and maintained in accordance with good air pollution practices.	<i>B. Braun demonstrates compliance by continued good operation and maintenance practices.</i>	<input checked="" type="checkbox"/> Continuous <input type="checkbox"/> Intermittent
<p><i>The following conditions apply to GRP3, which includes the following emission units:</i></p> <ul style="list-style-type: none"> ▪ <i>031 – BOILER – KEWANEE 19.5 MMBTU/HR</i> ▪ <i>032 – BOILER – KEWANEE 10.0 MMBTU/HR</i> <p><i>As presented in the amended TVOP renewal application, B. Braun has permanently discontinued operation of Source IDs 031 & 032.</i></p>				
GRP3 [25 Pa. Code §123.11] (Combustion units)	Section D - I. Restrictions - Emission Restriction(s) (#001)	The permittee may not permit the emission into the outdoor atmosphere of particulate matter from a combustion unit in excess of the following: (1) The rate of 0.4 pound per million Btu of heat input, when the heat input to the combustion unit in millions of Btus per hour is greater than 2.5 but less...	<i>N/A - B. Braun has permanently discontinued operation of Source IDs 031 & 032</i>	<input checked="" type="checkbox"/> Continuous <input type="checkbox"/> Intermittent
GRP3 [25 Pa. Code §123.22] (Combustion units)	Section D - I. Restrictions - Emission Restriction(s) (#002)	No person may permit the emission into the outdoor atmosphere of sulfur oxides, expressed as SO ₂ , from a combustion unit in excess of the rate of 4 pounds per million Btu of heat input over any 1-hour period.	<i>N/A - B. Braun has permanently discontinued operation of Source IDs 031 & 032</i>	<input checked="" type="checkbox"/> Continuous <input type="checkbox"/> Intermittent

Citation	Permit Section	Terms & Conditions Contained in the Permit	Means of Determining Compliance Status	Compliance with Terms & Conditions was:
GRP3 [25 Pa. Code §127.441] (Operating permit terms and conditions.)	Section D - I. Restrictions - Emission Restriction(s) (#003)	The type of fuel usage for each source of this source group shall be the following: (1) The 10.0 MMBtu/hr boiler shall be fired either with No. 6 fuel oil or natural gas. The primary fuel is the No. 6 fuel oil and the secondary fuel is natural gas. (2) The percent (%) by weight of sulfur content o...	N/A - <i>B. Braun has permanently discontinued operation of Source IDs 031 & 032</i>	<input checked="" type="checkbox"/> Continuous <input type="checkbox"/> Intermittent
GRP3 [25 Pa. Code §127.441] (Operating permit terms and conditions.)	Section D - IV. Recordkeeping Requirements (#004)	Prior to firing any deliveries of No. 6 fuel oil, the permittee shall either test the fuel oil to demonstrate compliance with the sulfur requirements or must receive a certification from the fuel supplier guaranteeing that the fuel meets the sulfur limit.	N/A - <i>B. Braun has permanently discontinued operation of Source IDs 031 & 032</i>	<input checked="" type="checkbox"/> Continuous <input type="checkbox"/> Intermittent



January 27, 2016

Mr. Mark Wejksznar
Pennsylvania Department of Environmental Protection
2 Public Square
Wilkes-Barre, PA 18711-0790

Enforcement Programs Section (3AT 13)
USEPA, Region III
1650 Arch Street
Philadelphia, PA 19103-2029

RECEIVED

JAN 28 2016

Air Protection Division

Re: Submittal of 40 CFR Part 63.10(e)(3)(i) and (vi)
Summary Report – Excess Emissions and CMS Performance Report
For Units Subject to 40 CFR Part 63, Subpart O
For the period of July 1, through December 31, 2015
B. Braun Medical, Inc., Allentown, Pennsylvania

Dear Sirs:

B. Braun Medical Inc. (B. Braun) operates a surgical and medical instrument apparatus manufacturing facility in Allentown, Pennsylvania. The B. Braun facility operates pursuant to the permit application shield provisions of Title V Operating Permit Number 39-00055, which was issued on January 13, 2010 and expired on January 13, 2015. A timely and complete Title V Renewal Application was submitted on July 9, 2014.

As required under the NESHAP for Ethylene Oxide Emission Standards for Sterilization Facilities (40 CFR Part 63, Subpart O), B. Braun Medical, Inc. (B. Braun) is submitting the attached completed semi-annual summary report in accordance with the requirements of 40 CFR 63.366 and 40 CFR 63.10(e)(3)(i) and (vi). As detailed at §63.10(e)(3)(vii), the total duration of excess emissions or process control system parameter exceedences for the reporting period was less than 1 percent of the total operating time and the CMS downtime for the reporting period was less than 5 percent of the total operating time for the reporting period. Therefore, the full excess emissions and CMS performance reports are not required to be submitted for this reporting period.

If you have any questions or require additional information please do not hesitate to contact me at (610) 596-2584.

Sincerely,

A handwritten signature in blue ink, appearing to read 'D. Lauer', with a large, stylized initial 'D'.

David R. Lauer
Environmental Health and Safety Manager, PA Operations

cc: Enf. Programs Sec.
Lindsey W. Kroos – All4 Inc.

SUMMARY REPORT –EXCESS EMISSIONS AND CONTINUOUS MONITORING SYSTEM PERFORMANCE

1.0 Name and Address (physical location) of the Source (40 CFR 63.10(e)(3)(vi)(A)):

B. Braun Medical, Inc.
901 Marcon Blvd.
Allentown, PA 18109

2.0 Identification of Each HAP Monitored at the Source (40 CFR 63.10(e)(3)(vi)(B)):

40 CFR Part 63, Subpart O requires control of ethylene oxide. Direct emission monitoring is not mandatory for ethylene oxide regulated in the standard. As a result, Continuous Parametric Monitoring Systems (CPMS) are specified in the standard to be used as a surrogate for measurement of HAPs. The following table describes the regulated HAPs, along with the required monitoring variable surrogates:

TABLE 2.1: REGULATED HAPs AND ASSOCIATED PARAMETRIC MONITORING VARIABLES

HAP or Other Requirement	Monitored Variables	Citation	Type of Monitoring System
Ethylene Oxide	Ethylene Glycol Concentration or Scrubber Tank Level	63.364(b)	CPMS
	Oxidation Temperature	63.364(c)	CPMS

3.0 Reporting Period (40 CFR 63.10(e)(3)(vi)(C)):

The reporting period covered by this report is from July 1 through December 31, 2015.

4.0 Description of Process Units (40 CFR 63.10(e)(3)(vi)(D)):

B. Braun is located in Allentown, Pennsylvania in Lehigh County. The Allentown facility manufactures surgical and medical instruments that are sterilized during the manufacturing process. Aside from ancillary equipment regulated by the facility's TVOP, and other small insignificant sources, the manufacturing process itself is not a source of air emissions. The sterilization procedure utilizes ethylene oxide (ETO) within a sterilization chamber. B. Braun maintains eight (8) ETO sterilization chambers (Units 101 – 108), which operate on a batch-cycle basis. From each sterilization chamber, the sterilized devices are directed to a common aeration chamber or room (Unit 110). The sterilization chambers and the aeration chamber are regulated by 40 CFR Part 63, Subpart O (Ethylene Oxide Emission Standards for Sterilization Facilities) and vented to emissions control equipment. Each sterilization chamber is equipped with a vacuum pump. During the course of each cycle, the vacuum pump pulls the gas stream containing ETO from the sterilization chamber to a common Deoxx unit, which employs a wet scrubbing technique for treatment of ETO emissions and achieves a 99% emission reduction. Once the majority of

the gas stream has been sent to the Deoxx unit, a small amount of residual, low concentration ETO gas is vented from the rear chamber exhaust vent of each sterilizer and exhausted to atmosphere through a common stack in accordance with 40 CFR §63.362(a). ETO emissions from the aeration chamber are routed to the Donaldson Catalytic Oxidizer, which utilizes a catalyst in conjunction with oxidation to control ETO emissions and achieves a 99% emission reduction or maintains an outlet ETO concentration of less than or equal to 1 ppmv in accordance with 40 CFR §63.362(d).

5.0 Emission and Operating Parameter Limitations Specified in Standard (40 CFR 63.10(e)(3)(vi)(E)):

The applicable emission limitations for sterilization facilities are detailed in 40 CFR 63.362 and are provided in Table 5.1 below.

TABLE 5.1: SUBPART O STANDARDS FOR B. BRAUN

Pollutant	Limit
Ethylene Oxide (Sterilization Chamber Vent)	99% emissions reduction
Ethylene Oxide (Aeration Room Vent)	99% emissions reduction or 1 ppmv, whichever is less stringent

The operating parameters required to be established under the Subpart O MACT standards are detailed at 40 CFR 63.364. The limitations for these parameters are required to be established during the performance testing in accordance with the requirements at 40 CFR 63.365 and the site specific performance test plan.

6.0 Monitoring Equipment Manufacturer and Model Number (40 CFR 63.10(e)(3)(vi)(F)):

Refer to Table 6.1 and Table 6.2 for the monitoring equipment manufacturer and model number.

TABLE 6.1: DEOXX UNIT MONITORING EQUIPMENT MANUFACTURER, MODEL NUMBER, AND LATEST CERTIFICATION DATE

Monitored Variables	Equipment Manufacturer	Model Number	Date of Last CMS Audit or Certification
Ethylene Glycol Concentration	Contract laboratory service	N/A	November, 2015
Scrubber Liquor Level	In house measurement	N/A	December, 2015

TABLE 6.2: DONALDSON CATALYTIC OXIDIZER MONITORING EQUIPMENT MANUFACTURER, MODEL NUMBER, AND LATEST CERTIFICATION DATE

Monitored Variables	Equipment Manufacturer	Model Number	Date of Last CMS Audit or Certification
Oxidation Temperature	Wonderware Software System	N/A	July, 2015

7.0 Date of Latest CMS Certification or Audit (40 CFR 63.10(e)(3)(vi)(G)):

Please refer to Tables 6.1 and 6.2 for the date of the latest CMS certification or audit.

8.0 Total Operating Time for Each Source (40 CFR 63.10(e)(3)(vi)(H)):

Please refer to the attached emission data (Attachment 1) and CMS performance summaries (Attachment 2).

9.0 Emission Data Summary (40 CFR 63.10(e)(3)(vi)(I)):

The emission data summary for this reporting period is provided in Attachment 1 of this report.

10.0 CMS Performance Summary (40 CFR 63.10(e)(3)(vi)(J)):


The CMS performance summary for this reporting period is provided in Attachment 2 of this report.

11.0 Description of Changes in CMS, Processes or Controls Since Previous Reporting Period (40 CFR 63.10(e)(3)(vi)(K)):

No changes in the CMS, process, or controls have occurred since the previous reporting period.

12.0 Certification and Report Date (40 CFR 63.10(e)(3)(vi)(L) and (M)):

I certify, based on a reasonable inquiry of the persons responsible for preparing this semi-annual report that the information provided is, to the best of my knowledge and belief true, accurate, and complete.



Rex Boland
Vice President/General Manager, PA Operations

Report Date: 1-27-16

Attachment 1
Summary of Excess Emissions

Donaldson Catalytic Oxidizer Unit (Aeration Room Vent)

B. Braun Medical Inc. - Allentown, PA

MACT Parameter Exceedence Summary for Reporting Period: 07/1/2015-12/31/2015

Attachment # 1

Donaldson Catalytic Oxidizer Unit Source Operating Time = 256023 [minutes]				Excess Emissions Summary							
Monitored Variable	Limit	Averaging Time		Startup or Shutdown (min)	Control Equipment Malfunction (min)	Process Equipment Malfunction (min)	Other Known Cause (min)	Other Unknown Cause (min)	Total Duration of Excess Emissions (min)	% Excess Emissions ^(a,b)	Is the % Excess Emissions Greater than 1%?
Minimum Oxidation Temperature	253/258 deg. F	15-minute values or shorter, compute and record 24-hour average, when catalytic oxidizer is operated	Duration of Events Where SSM Plan Was Followed	N/A	N/A	N/A	N/A	N/A	N/A		
			Duration of Events Where SSM Plan Was Not Followed	N/A	N/A	N/A	N/A	N/A			
			Duration of Exceedences Not a Result of a Startup, Shutdown, or Malfunction Event						0	0.00	NO

^(a) Excursions caused by Malfunction events are not counted toward the Excess Emissions total duration and 1% full Excess Emission Report threshold level as the limits do not apply during Malfunction events (63.162(b))
^(b) Per §63.10(e)(3)(vi) excess emissions and monitor downtime was calculated based on the total duration of excess emissions or monitor downtime per the total control equipment operating time during the reporting period.

Donaldson Catalytic Oxidizer Unit Operating Time
 (minutes per semi-annual time period): 256,023

DEOXX Unit (Sterilization Chamber Vent)
B. Braun Medical Inc. - Allentown, PA

MACT Parameter Exceedence Summary for Reporting Period: 07/1/2015-12/31/2015

Attachment # 1

DEOXX Unit Source Operating Time = 262950 [minutes]			Excess Emissions Summary							
Monitored Variable	Limit	Averaging Time	Startup or Shutdown (min)	Control Equipment Malfunction (min)	Process Equipment Malfunction (min)	Other Known Cause (min)	Other Unknown Cause (min)	Total Duration of Excess Emissions (min)	% Excess Emissions ^(a,b)	Is the % Excess Emissions Greater than 1%?
Maximum Scrubber Liquor Level	126 inches	once per week, when scrubber is operated	N/A	N/A	N/A	N/A	N/A	N/A		
			N/A	N/A	N/A	N/A	N/A	N/A		
								0	0.00	NO

^(a) Excursions caused by Malfunction events are not counted toward the Excess Emissions total duration and 1% full Excess Emission Report threshold level as the limits do not apply during Malfunction events [63.362(b)]

^(b) Per §63.10(e)(3)(vii) excess emissions and monitor downtime was calculated based on the total duration of excess emissions or monitor downtime per the total control equipment operating time during the reporting period.

DEOXX Unit Operating Time

(minutes per semi-annual time period):

262,950

Attachment 2
CMS Performance Summaries

DEOXX Unit (Sterilization Chamber Vent)

B. Braun Medical Inc. - Allentown, PA

MACT Parameter Monitor Performance Summary for Reporting Period: 07/1/2015-12/31/2015

Attachment # 2

Attachment # 2

DEOXX Unit Source C17Operating Time = 262950 [minutes]			CMS Downtime Summary							Is the % Excess Emissions Greater than 5%?
Monitored Variable	Limit	Averaging Time	Monitoring Equipment Malfunctions (min)	Non-Monitoring Equipment Malfunctions (min)	"Non-(a) Routine" QA/QC Calibrations (min)	Other Known Causes (min)	Other Unknown Causes (min)	Total Duration of CMS Downtime (min)	% CMS Downtime	
Maximum Scrubber Liquor Level	126 inches	once per week, when scrubber is operated	0	0	0	0	0	0	0.00	NO

(a) "Routine calibrations" is defined as normal zero and high level checks. These periods are not included in CMS downtime pursuant to 40 CFR 63.10(e)(5) and EPA's MACT reporting guidance (August 2, 2002 Version).

DEOXX Unit Operating Time

(minutes per semi-annual time period): 262,950

MACT Parameter Monitor Performance Summary for Reporting Period: 07/1/2015-12/31/2015

Attachment # 2

[illegible]

⁽¹⁾ "Routine calibrations" is defined as normal zero and high level checks. These periods are not included in CMS downtime pursuant to 40 CFR 63.10(c)(5) and EPA's MACT reporting guidance (August 2, 2002 Version)

Donaldson Catalytic Oxidizer Unit Operating Time
(minutes per semi-annual time period): 256,023